

§ 882.5975 Human dura mater.

(a) *Identification.* Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Human Dura Mater.” See § 882.1(e) for the availability of this guidance.

(c) *Scope.* The classification set forth in this section is only applicable to human dura mater recovered prior to May 25, 2005.

[68 FR 70436, Dec. 18, 2003, as amended at 76 FR 36993, June 24, 2011]

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Sec.

884.1 Scope.

884.3 Effective dates of requirement for pre-market approval.

884.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Obstetrical and Gynecological Diagnostic Devices

884.1040 Viscometer for cervical mucus.

884.1050 Endocervical aspirator.

884.1060 Endometrial aspirator.

884.1100 Endometrial brush.

884.1175 Endometrial suction curette and accessories.

884.1185 Endometrial washer.

884.1300 Uterotubal carbon dioxide insufflator and accessories.

884.1425 Perineometer.

884.1550 Amniotic fluid sampler (amniocentesis tray).

884.1560 Fetal blood sampler.

884.1600 Transabdominal amnioscope (fetoscope) and accessories.

884.1630 Colposcope.

884.1640 Culdoscope and accessories.

884.1660 Transcervical endoscope (amnioscope) and accessories.

884.1690 Hysteroscope and accessories.

884.1700 Hysteroscopic insufflator.

884.1720 Gynecologic laparoscope and accessories.

884.1730 Laparoscopic insufflator.

Subpart C—Obstetrical and Gynecological Monitoring Devices

884.2050 Obstetric data analyzer.

884.2225 Obstetric-gynecologic ultrasonic imager.

884.2600 Fetal cardiac monitor.

884.2620 Fetal electroencephalographic monitor.

884.2640 Fetal phonocardiographic monitor and accessories.

884.2660 Fetal ultrasonic monitor and accessories.

884.2675 Fetal scalp circular (spiral) electrode and applicator.

884.2685 Fetal scalp clip electrode and applicator.

884.2700 Intrauterine pressure monitor and accessories.

884.2720 External uterine contraction monitor and accessories.

884.2730 Home uterine activity monitor.

884.2740 Perinatal monitoring system and accessories.

884.2800 Computerized labor monitoring system.

884.2900 Fetal stethoscope.

884.2960 Obstetric ultrasonic transducer and accessories.

884.2980 Telethermographic system.

884.2982 Liquid crystal thermographic system.

884.2990 Breast lesion documentation system.

Subpart D—Obstetrical and Gynecological Prosthetic Devices

884.3200 Cervical drain.

884.3575 Vaginal pessary.

884.3650 Fallopian tube prosthesis.

884.3900 Vaginal stent.

Subpart E—Obstetrical and Gynecological Surgical Devices

884.4100 Endoscopic electrocautery and accessories.

884.4120 Gynecologic electrocautery and accessories.

884.4150 Bipolar endoscopic coagulator-cutter and accessories.

884.4160 Unipolar endoscopic coagulator-cutter and accessories.

884.4250 Expandable cervical dilator.

884.4260 Hygroscopic Laminaria cervical dilator.

884.4270 Vibratory cervical dilators.

884.4340 Fetal vacuum extractor.

884.4400 Obstetric forceps.

884.4500 Obstetric fetal destructive instrument.

884.4520 Obstetric-gynecologic general manual instrument.

884.4530 Obstetric-gynecologic specialized manual instrument.

884.4550 Gynecologic surgical laser.

884.4900 Obstetric table and accessories.